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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/674,597

04/09/2001

Zheng Xin Dong

00537-169002

1308

37903 7590 01/25/2007  
DAWN JANELLE AT  
BIOMEASURE INC.  
27 MAPLE STREET  
MILFORD, MA 01757

EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/674,597	<b>Applicant(s)</b> DONG ET AL.	
	<b>Examiner</b> Sandra Wegert	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-6 and 8-51 is/are pending in the application.
- 4a) Of the above claim(s) 8,16-22,30-47 and 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-15,23-29 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Detailed Action*****Status of Application, Amendments, and/or Claims***

The Amendments and Response, submitted 30 June 2006, have been entered. Claims 9-14 have been amended. Claims 48-51 are new. New Claims 49-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Thus, Claims 8, 16-22, 30-47 and 49-51 are withdrawn in this Office Action. Applicants traversed the restriction requirement of 8/19/03 as it pertains to the PTH2 analogues, arguing that the examiner has failed to demonstrate that the analogues are patentably distinct (Response, 30 June 2006, p. 27). However, the sequences are independent and distinct products having characteristic differences in structure and function and having different uses. Compare, for example, SEQ ID NO: 16 with SEQ ID NO: 17. The resultant similarity, not counting gaps, is approximately 14%. In addition, the side chains (A1-A38) attached to the elected SEQ ID NO's comprise an almost unlimited variety and number of residues. A complete search of the art for each encompassed sequence, each resultant analogue, as well as full database searches, constitute an undue burden if all sequences are searched together.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 9-15, 23-29 and 48 are under examination in the Instant Application.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

**Withdrawn Objections And/or Rejections**

***Withdrawn Objections***

The objection to New Matter added to Claims 9, 10, 13 and 14 is *withdrawn*. The objection was made because Applicants had added the word "human" to claims, where referring to the PTH receptor and analogues of PTH (15 November 2004). Applicants pointed out that the "human" receptor and analogues are contemplated on p. 20 of the Specification as originally filed (Remarks, p. 27, 30 June 2006).

***Withdrawn Rejections-***

The rejection of claims 1-3 and 7 under 35 U.S.C. 102(b) for being unpatentable over Chorev, et al, (1990, Biochemistry, 29: 1580-1586) is *withdrawn*. Applicants cancelled claims 1-3 and 7 in the Response filed 30 June 2006.

Likewise, the rejection of claims 1-3 under 35 U.S.C. 102(b) for being unpatentable over Rosenblatt, et al, 1991 (US Patent 5,001,223) is *withdrawn*. Applicants cancelled claims 1-3 in the Response filed 30 June 2006.

***35 USC § 112, second paragraph – Indefiniteness***

The rejection of Claims 7, 9, 10, 12, 13 and 14 for improper Markush groupings is *withdrawn*. Applicants cancelled claim 7, and amended remaining claims to recite "and" rather than "or" before the last item listed in each claim (10 December 2005).

The rejection of Claims 7, 9, 10, 12, 13 and 14 for reciting a term near the end of each claim that had no antecedent basis ("the compound") is *withdrawn*. Applicants cancelled claim 7 and amended the claims to recite the same PTH analogues found in the preamble of the claims (10 December 2005).

### **Maintained/New Objections and/or Rejections**

#### ***Claim Objections-***

The objection to Claims 9, 10, 13-15 and 23-29 for reciting or encompassing non-elected inventions is *maintained*. Applicants amended Claims 11 and 12 so that they recite only the elected subject matter, but other claims were not so amended and remain objected to.

#### ***-Duplicate claims***

Applicant is advised that should claim 11 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

#### ***Claim Rejections - 35 USC § 112, first paragraph-Written Description***

Claims 9, 10, 13-15 and 23-29 are rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for this rejection

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under 35 U.S.C. § 112 are set forth at pp. 4-7 of the previous Office Action (11 April 2005).

This rejection no longer applies to Claims 11 and 12 (30 June 2006) which have been amended, or to claims 1-3 and 7, which have been cancelled (30 June 2006).

The claims are directed to PTH analogues, truncated analogues, and compositions of PTH analogues. The claims recite short peptides in which almost every residue may be substituted from a large set of typical amino acids, atypical amino acids or amides or even deleted.

The specification teaches several specific polypeptides (for example: SEQ ID NO: 16). However, the specification does not teach functional or structural characteristics of all compounds and all polypeptides encompassed by the claims (i.e., that bind selectively to the human PTH2 receptor). The description of one polypeptide PTH analogue (SEQ ID NO: 16) is not adequate written description of an entire genus of functionally equivalent polypeptides and compounds.

Applicants reassert their arguments set forth in the Response submitted 15 November 2004 that the instant application meets the requirements of 35 U.S.C. §112, first paragraph- Written Description- and cite case law as support that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact (*in re* Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976); *Ex parte* Sorenson, 3 USPQ2d 1462, 1463 (Bd. Pat. App. & Inter. 1987)). The examiner agrees with this depiction of the Written Description analysis. The inquiry into whether the Written Description requirement is met *should* be determined on a case-by-case basis (*in re* Wertheim) and has been in this instance. *Ex parte* Sorenson, on the other hand, only concerns the language used to describe the invention, stating: "the specification need not describe the claimed invention in *ipsis verbis* to comply with

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the written description requirement." Put more simply, the specification does not have to describe the claimed invention using the very same words as those used in the claims, just language with equivalent meaning. Since the claim language in this case is very similar to the language used in the Disclosure, and since this issue was not raised by the examiner, *Ex parte* Sorenson is not pertinent.

Applicants also discussed *In re Smythe*, again, relative to supposed literal definitions of claimed species of the invention (Remarks, p. 31, 30 June 2006) (*In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ (BNA) 279, 284-85 (CCPA 1973)). *In re Smythe* was discussed in the last Office Action pertaining to the Written description rejection (11 April 2005) and will not be discussed further here.

To fulfill the written description requirement, a patent specification must describe an invention in sufficient detail such that one skilled in the art could clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 U.S.P.Q.2d at 1966. However, Applicants have not described or shown possession of a commensurate number of species of polypeptides *that selectively bind the PTH2 receptor*. Alternatively, the applicants could have described and used a representative number of

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species to demonstrate that they are in possession of a genus of PTH2 compounds that function in the same way (e.g., that are selective for the PTH2 receptor). They have not done so.

As discussed in the previous Office Action (11 April 2005)) even a very skilled artisan could not envision the detailed chemical structure of all or a significant number of encompassed PTH2 compounds, and therefore, would not know how to use them. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The product *itself* is required. Recitation of the phrases "human PTHrP analogue" (Amended claims, 15 November 2004), and "where said analogue is a selective PTH2 receptor agonist" are not adequate to describe the claimed PTHrP analogue, since there was no reduction to practice to support the qualifying phrases in the claims. Applicants neither made nor tested variant PTHrP analogues, and as recited in the current Written Description Guidelines, Applicants must have invented the subject matter that is claimed and must be in "possession" of the claimed genus (Federal Register, 2001, Vol. 66, No. 4, pages 1099-1111, esp. page 1104, 3rd column).

Applicants argue that there was a reduction to practice in describing the PTH2 peptides, in that there are examples of binding experiments in the Specification at pages 21-23 (Remarks, p. 33). However, unlike the examples which describe *synthesis* of the 4 peptides of Examples 2-5, the cell-binding experiments are hypothetical. No data were collected concerning the binding activities, or relative binding activities, of the PTH2 peptides. Furthermore, even if the four species had been tested, four species is insufficient to support description of the broadly-claimed genus. Thus, this genus was not adequately described.

***Claim Rejections- Double-Patenting***

The rejection of Claims 9-15 and 23-29 under the judicially created doctrine of double patenting, is *maintained*. The rejection was made over claims 1-23 of U. S. Patent No. 5,723,577.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claimed analogues of the instant Application are similar in structure to the claimed peptides and peptide analogues of Patent 5,723,577. The claimed analogues of Patent 5,723,577 are similar to the PTH analogues of the instant Application and would therefore possess the same inherent characteristics such as PTH2 binding affinity and efficacy ( $K_d$  and  $EC_{50}$ , respectively; see Table I of Patent 5,723,577).

Applicants argue essentially (Revised Remarks, p. 34, 30 June 2006) that the claims of the instant Application recite the functional limitation of selectively binding to the PTH2 receptor, thus distinguishing them from the claims of the '577 patent. Applicants state: "a compound of the instant application has to have been synthesized and tested positive for selective binding to the PTH2 receptor for the compound to fall within the claims of the instant application" (p. 34, bottom). The examiner disagrees. In the first place, as discussed above, there was no reduction to practice in the instant application as far as measurement of PTH2 receptor binding. Nor were comparisons made between PTH2 receptor binding of the recited compounds and binding to other PTH receptors. It is not known if the claimed compounds are selective for the PTH2 receptor, or even how one would know from binding data what is meant

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in the claims by the word "selective." In addition, by making the argument that "a compound of the instant application has to have been synthesized and tested positive" [ ] for the compound to fall within the claims of the instant application," Applicants are not consistent with their argument (above) regarding Written Description where they contend that it is not necessary to reduce an invention to practice if it is simply well-described by the specification.

Furthermore, Applicants are claiming the actual compounds, not methods that make use of the functional limitation. Many of the peptides claimed are obvious variants of peptides in the '577 patent. Applicants cannot negate the obviousness of the present invention by inserting additional language not found in the '577 patent. The compounds of the '577 patent would inherently possess the same properties as those of the present invention, whether that language was used or not (*in re Skoner*, 517 F.2d 947, 950 (C.C.P.A. 1975), 186 U.S.P.Q. 80, 82 (1975)). Mere similarity of structure is sufficient to establish obviousness. The burden thus shifts to the Applicants to provide evidence that the peptides of the '577 patent do NOT possess the functional limitations recited in the Applicants claims (see *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), and MPEP § 2112.01 and § 2141).

Applicants arguments concerning *In re Schneller* (Remarks, p. 37) are essentially correct in that the PTH2 receptor was not known at the time of filing of the '577 patent. Thus the newly-discovered property of binding the PTH2 receptor could not have been included in the patent. However, this does not change the essential point of the rejection that "the discovery of a previously unappreciated property of a prior art composition [ ] does not render the old composition patentably new to the discoverer" (MPEP § 2112-I).

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Applicants also discuss what is meant by selective binding and refer to pp. 2 and 3 of the Specification (Remarks, p. 35). While the Specification does discuss the properties of the compounds in terms of binding both PTH1 and PTH2, no data was generated that might illuminate the differences between and among the "selective" compounds. Furthermore, since the structures of many of the peptides are similar in the '577 patent, it might be expected that some of those compounds would likewise be "selective" for the PTH2 receptor as well.

The rejection of Claims 9-15 and 23-29 under the judicially created doctrine of double patenting, is *maintained*. The rejection was made over claims 1-16 of U. S. Patent No. 5,717,062. Applicants make the same arguments as presented above for the rejection over the '577 patent and also add that the '062 patent requires that the side chain residues of A13 and A17, A26 and A30 or A13 and A17 and A26 and A30 be linked by a disulfide bond or an amide bond (patent, column 25) and that this limitation was not found in the claims of the instant Application (Remarks, p. 38). However, the instant claims are so broad that there are no limitations whatsoever that would exclude the presence of such bonds nor preclude the use of residues that can form disulfide or amide bonds. Silence in the instant claims does not negate this property as obvious over the '062 patent. Additionally, it should be noted that both A13 and A26 both recite "HN-CH((CH<sub>2</sub>)<sub>n</sub>NH-R<sup>4</sup>)-C-(O)" as a possible residue, which can bind to the amino acid residues in positions A17 and A30, forming an amide bond.

The rejection of Claims 9-15 and 23-29 under the judicially created doctrine of double patenting, is *maintained* over US Patent No. 5,955,574 for reasons of record. Applicants stated

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that the rejection was made in error and did not discuss it further (Remarks, p. 39). The rejection recites and discusses claims 1-14 of U. S. Patent No. "5,995,574." This was an obvious misprint of US Patent No. 5,955,574, which is the Applicants' own patent and is recited in the IDS of 14 May 2004. Applicant argued against the related rejection for US Patent No. 5,955,574 (Dong, et al) under 35 U.S.C. § 102(e) below.

### **35 U.S.C. § 102**

The rejection of Claims 9-15 and 23-29 under 35 U.S.C. 102(b) as being unpatentable over Gardella, et al, (1996, J. Biol. Chem., 271(33): 19888-19893) is *maintained*. Gardella, et al disclose some human PTH analogues that are highly-selective for the PTH2 receptor (see Table I and Figure 2B), some that are not as selective, and some with intermediate selectivities. This reference meets the limitations of Claims 9-15 and 23-29 of "human PTH [ ] analogue" and PTH analogues comprising hPTH (1-31)-NH<sub>2</sub>. Because of the similarity between the peptides disclosed in Gardella, et al and the instant Application, the peptides disclosed in the reference will have the same inherent binding properties at the PTH2 receptor as those of the instant Application.

Applicants argue that the claims of the instant Application specifically disclaim those particular analogues that Gardella, et al found to be selective for the PTH2 receptor (p. 40, 30 June 2006). However, the instant claims are so broad that they do not disclaim any but a few of the analogs in Gardella, et al. In addition, the paper discloses many analogues, and teaches how to make many more, that would bind with higher affinity to the PTH2r than to the PTHr, not just PTH analogues comprising TRP at position 23 or His at position 5. For example, analogs 1, 3, 4,

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5, 8, 9, 10, 13, 14 and 15 in Table 1 all bind the PTH2 receptor with higher affinity than they bind the PTH receptor. Keeping in mind that "selective" does not mean exclusive (Specification, bottom of p. 3), about half the analogues used or taught in Gardella, et al bind with greater affinity to PTH2r than to PTHr.

Additionally, it should be kept in mind that the instant claims require the peptides to "selectively bind to the PTH2 receptor" (see amended Claim 9, for example). If, as applicants suggest, Gardella et al is not prior art because the researchers disclosed those specific peptides that "stimulated the PTH2 receptor" (p. 40, 30 June 2006, described above) and applicants are specifically disclaiming those particular analogues, then the remaining claimed analogues would not fulfill the requirements of the claims themselves of selectively binding the PTH2 receptor- in other words they would not be enabled.

Applicants argue presumably against the previous restriction requirement for the instant Application (p. 41, top, 30 June 2006), implying that use of the Gardella, et al reference as prior art negates the statement made by the examiner that the claimed peptides are structurally and functionally distinct. This argument has been considered, but is not deemed persuasive. Firstly, the restriction requirement is based upon the fact that the sequences in the instant application are different from *each other*, not different from sequences disclosed in the prior art. It is not known, given the chance, how the examiner might have "restricted" the peptides in the prior art publication. But, whether Gardella, et al disclose one genus or invention or several makes no difference to either the restriction requirement in this application or the art rejection. It is interesting to note however that the prior reference discloses a structurally wide variety of peptides with wide ranges of binding characteristics, not only encompassing the applicants'

claimed invention but demonstrating that minor changes in the sequence of "PTH" peptides produce significant changes in function.

The rejection of Claim 9 under 35 U.S.C. 102(b) as being unpatentable over Neugebauer and Willick, (1993, Peptides 1992, C.H. Schneider and A.N. Eberle (eds), ESCOM Science Publishers) is *maintained*. This rejection no longer applies to claim 1-3 and 7, which have been cancelled (30 June 2006). Neugebauer and Willick make and disclose PTH analogues comprising hPTH (20-34).

Applicants argue that the peptides disclosed in Neugebauer and Willick would not selectively bind to the PTH2 receptor. However, claim 9 recites that residues 1-19 of the peptide can be "deleted" and side chains R1 and R2 can be "H." The peptide with these particular deletions and hydrogen side chains reads *exactly* on the Formula 1 peptide disclosed in Neugebauer and Willick. And since that peptide in the reference is the same as that encompassed by claim 9 it will have the same inherent properties as that of the instant Application. The burden thus falls on the Applicants to demonstrate that the prior art does *not* have that inherent property (see *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)).

Likewise the rejection of claim 9 under 35 U.S.C. 102(b) for being unpatentable over Willick, et al, 1996 (U.S. Patent 5,556,940) is *maintained*. This rejection no longer applies to claim 1-3 and 7, which have been cancelled (30 June 2006). Willick, et al disclose human PTH peptides fully encompassed by claim 9. For example, they recite peptides that comprise hPTH

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(1-31)-NH<sub>2</sub>, and they recite and make use of analogues from hPTH (1-28)-NH<sub>2</sub> to hPTH (1-31)-NH<sub>2</sub>, as well as all sequences from [Leu<sup>27</sup>]-hPTH-(1-28)-NH<sub>2</sub> to [Leu<sup>27</sup>]-hPTH-(1-33)-NH<sub>2</sub>.

This reference meets the limitations of Claim 9 of "human PTH [ ] analogue" and PTH analogues comprising hPTH (1-31)-NH<sub>2</sub> and the list of variable residues A1-A38. Because of the similarity between the peptides disclosed in Patent 5,556,940 and the instant Application, and the fact that the exact same peptides are encompassed by claim 9 as those disclosed in the patent, the peptides disclosed in the patent will have the *same* inherent binding properties at the PTH2 receptor as those of the instant Application. Applicants argue that the peptides disclosed in the patent would not selectively bind to the PTH2 receptor. However, if they are the *same* peptides they would indeed bind receptors in the same way as those disclosed in claim 9. It is true that the newly-discovered property of binding the PTH2 receptor could not have been included in the patent. However, this does not change the essential point of the rejection that "the discovery of a previously unappreciated property of a prior art composition [ ] does not render the old composition patentably new to the discoverer" (MPEP § 2112, I, referring to *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977) and *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004)).

The rejection of Claims 9-15 and 23-29 under 35 U.S.C. 102(e) as being anticipated by US Patent 5,717,062 (Chorev) is *maintained*. The rejection was made over claims 1-16 of U. S. Patent No. 5,717,062. Applicants make the same arguments as presented above for the rejection over the '940 patent and also add that the '062 patent requires that the side chain residues of A13 and A17, A26 and A30 or A13 and A17 and A26 and A30 be linked by a disulfide bond or an

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amide bond (patent, column 25) and that this limitation was not found in the claims of the instant Application (Remarks, p. 43). However, the instant claims are so broad that there are no limitations whatsoever that would exclude the presence of such bonds nor preclude the use of residues that can form disulfide or especially amide (C-N) bonds. Silence in the instant claims does not negate this property as obvious over the '062 patent. Additionally, it should be noted that both A13 and A26 both recite "HN-CH((CH<sub>2</sub>)<sub>n</sub>NH-R<sup>4</sup>)-C-(O)" as a possible residue, which can bind to the amino acid residue in positions A17 and A30, forming an amide bond.

The rejection of claims 9-15 and 23-29 under 35 U.S.C. 102(e) as being anticipated by US Patent 5,955,574 (Dong, et al) is *maintained*. See the obviousness-type double patenting rejection above. Applicants make the same arguments as presented above for the rejection over the '062 patent. They also add that not all the elements of the rejected instant claims are disclosed or taught by the 574 patent, but did not specify the missing elements (p. 44, Remarks, 30 June 2006).

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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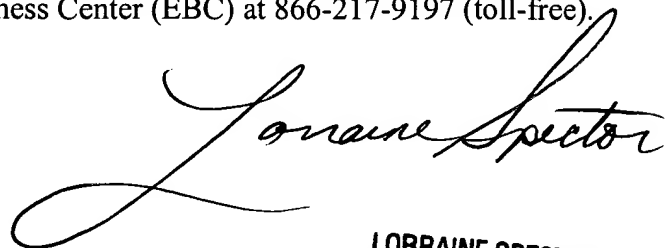
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire Later than SIX MONTHS from the mailing date of this final action.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW  
8 January 2006



**LORRAINE SPECTOR  
PRIMARY EXAMINER**